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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/777,664	02/07/2001	Sandhya Mishra	2001_0120A	9236

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EXAMINER

MARX, IRENE

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 06/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/777,664	MISHRA ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-18 is/are pending in the application.
- 4a) Of the above claim(s) 13-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 12, and 16-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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The application should be reviewed for errors. Error occurs, for example, in the spelling of "cyanophyceae" and "Nostocaceae".

In keeping with scientific custom, the names of genera and species of microorganisms should be underlined or italicized throughout the specification and claims.

The amendment filed 5/30/03 is acknowledged. Claims 21-38 are being considered on the merits.

The amendment filed 5/30/03 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The material to be added at page 13 regarding the nature of the deposited "Consortium". There is no clear correlation between the material designated "Consortium" in the as-filed specification and the material now deposited.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for the steps recited in claim 21 that include inoculation on a cloth permeable to brine but that retains the cyanobacteria, contacting the cloth for an optimum period with raw brine, removing the cloth; immersing the cloth for an optimum period in dilute brine; recycling the cloth, etc. As a matter of fact, no mention of any cloth is found in the as filed written disclosure.

No basis or support is found in the present specification for a "consortium" of "Lyngbya sp., Oscillatoria sp., Anabaena sp., Spirulina sp. and Synechocystis sp. (ATCC PTA-4603)." The

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as filed specification is directed to "Consortium" and indicates results with each of the species *per se*.

Therefore, this material raises the issue of new matter and should be deleted.

Claim Rejections - 35 USC § 112

Claims 21-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in the recitation of "optimum period" regarding items (iii) and (iv). One of ordinary skill in the art cannot readily ascertain the time period intended. Moreover, the "optimum time" appears to depend on salt concentration and the nature and identity of the Cyanobacteria used. Also the step of "ooze out" in claims 21 and 36 does not particularly set forth what is intended in the context of a "cloth" immobilized culture.

Claims 28-29 are confusing, since there does not appear to be basis for a "multiplication" step in claim 21.

In claim 30, it is not clear at what point in time "the brine treated by the method" is intended. Also the step of "eliminate spontaneously" cannot be ascertained in the context of a bioremediation method by Cyanobacteria.

Claim 32 requires a concentration of fresh weight of cyanobacteria of 1-10 g/L. How much is required for the process of claim 21? Also in claim 32 it is unclear what is intended by "the contact time is based on the duration of the lag and log phases of its activity for maximum uptake of calcium ions" The antecedent basis for "its activity" is uncertain. In addition, while the basis of the "contact time" is of interest, it appears that the length of the contact time is more pertinent to the process of the invention, as recited in claim 33.

In claim 36 it is uncertain how the exposure to dilute brine makes the cyanobacteria "suitable for recycle".

Claims 21-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for strain *Lyngbya aestuarii* SM-1, does not reasonably provide enablement for "marine cyanobacteria obtained from hyper-saline habitat" or "hyper-saline environments in

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the west seacoast of India". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

From the record of the present written disclosure, strain *Lyngbya aestuarii* SM-1, is the only strain of Cyanobacteria shown to be capable of the reduction of calcium ions in brine in the manner claimed. Other strains were shown in the process. However, these are unidentified strains of various genera, the nature and identity of which is unknown. In addition, there is no indication as to availability to the public for these strains. With respect to the "Consortium" mentioned in the specification and now claim designated, there is insufficient information in the as-filed specification regarding the nature of this group of microorganisms.

Therefore strain *Lyngbya aestuarii* SM-1 is the only strain enabled by the present specification for the process as claimed, provided, of course, that all deposit requirements are met.

For compliance with the rules, it must be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) **and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.** MPEP 2403.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

Thus, it would require undue experimentation for one skilled in the art to determine which other strains of Cyanobacteria or members of the recited genera would be suitable for the claimed invention, in view of the diversity of strains encompassed by Cyanobacteria and the difficulty in isolating strains from nature, especially in the absence of a specific screening assay, and the requirements argued for resistance to concentrations of salt as high as 22% and which are suitable for recycling after calcium removal from brine (Response, page 6, paragraph 3). *Ex parte Jackson*, 217 U.S.P.Q. 804 (Bd. App. 1982).

Undue experimentation would also be required to determine which strains are properly members of the recited genera in the "Consortium" as now deposited.

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Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary to isolate strains of hyper-saline environments, particularly in India; the limited amount of guidance and limited number of working examples with respect to the isolation process in the specification; the nature of the invention and the state of the prior art. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Thus, the scope of the claims is not commensurate with the teachings of enablement of the specification.

The rejections under 35 U.S.C § 102 and 103 are withdrawn in view of applicant's amendments, but will be reinstated as appropriate upon removal of the new matter.

The claims 21-38 are free of the art of record because the process steps used in the prior art regarding the removal of calcium from brine differ from those claimed herein. There would have been no motivation for one of ordinary skill in the art to modify the processes of the prior art relating to calcium removal by Cyanobacteria to use a cloth to immobilize the bacteria and to recycle them as claimed.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.



IRENE MARX
PRIMARY EXAMINER